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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/677,672	10/02/2000	Jean-Christophe Francis Audonnet	454313-3160	3424

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NEW YORK, NY 10151

EXAMINER

NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 07/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/677,672

Applicant(s)
Audonnet

Examiner
Dave Nguyen

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1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 12, 2003
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1-11. 14 have been amended, claims 15-18 have been added by the amendment dated May 12, 2003.

Issue of species Restriction.

Applicant again presents an argument for the same reasons as set forth previously, and the argument is found partially persuasive for examination of equine rhinopneumoonia virus, equine influenza virus, Eastern encephalitis virus, Western encephalitis virus, Venezueulan encephalitis, rabies virus and FIV. In addition, EMA or Carbopol® will be searched in this instant office action. Thus, the above named species will be searched in this office action.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

To the extent that applicant has not acknowledges on record that the priority French application is present in any of the parent case, or that the French priority document is not present or accessible for the examiner's consideration, claims 1, 2, 4, 10, 11, 12, as generically claimed, are rejected under 35 USC 102(e) as being anticipated by Ross (US Pat No. 6,444,799).

Ross teaches a DNA vaccine composition comprising an adjuvant chosen from the polymers of acrylic or methacrylic acid and EMA (copolymers of maleic anhydride and alkenyl derivative) and a plasmid vector encoding a *P. gingivalis* polypeptide, e.g., column 2, lines 45-67, column 5 bridging column 6, and column 6, lines 27-37. As such, Ross does teach a method of employing the adjuvant to enhance the efficacy of the DNA vaccine *in vivo*.

Applicant asserts that the French priority document is submitted together with its English translated copy, however, such documents are not present at the time of preparing this office action, and as such, the rejection is maintained for the reasons of record.

To the extent that claims 1-14 embraced FIV DNA vaccine, the Chavez reference is applicable as

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prior art under 35 USC 102(e).

Claims 1-14 are rejected under 35 USC 102(e) as being anticipated by Chavez (US Pat No. 6,300,118).

Chavez teaches a DNA vaccine containing a plasmid encoding a FIV antigen in combination with EMA or Carbopol®, see column 3, first full par., and column 4. The amount of adjuvant that can be present in the adjuvant/DNA vaccine mixture is disclosed on column 7.

As such, the claims are anticipated by Chavez.

Claims 1-18 are rejected under 35 USC 103(a) as being unpatentable over any of Davis (US 2002/0164341 A1), Olsen (US 2001/0007860), or Crabb (US 5,922,237) taken with any of Miles Inc. (EP 0 532 833 A1), Lowell, Chavez, Gicquel (US 2001, 0024653 A1) or Wasmoen (US 5,989,562).

Davis teaches a DNA vaccine comprising a polymer composed adjuvant (par. 0008, page 1, par. 0070-71, page 8, entire page 14. The antigen encoded by the DNA vaccine can be a pathogen antigen obtained from equine rhinopneumoonia virus, equine influenza virus, Eastern encephalitis virus, Western encephalitis virus, Venezueulan encephalitis, rabies virus and FIV.

Olsen teaches a DNA vaccine comprising an antigen encoded DNA obtained from equine influenza virus (page 10 bridging page 11).

Crabb teaches a DNA vaccine comprising a DNA coding for equine influenza virus, equine rhinovirus coding antigen (column 21).

Davis, Olsen and Crabb do not teach an incorporation of EMA or Carbopol® as adjuvants in the DNA vaccine composition so as to enhance its vaccinated effect.

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However, at the time the invention was made, Miles Inc. teaches a combination vaccine comprising an adjuvant preferably a Carbopol acrylic-based adjuvant is effective for use in protecting horse against EHV (entire document, abstract, page 4, lines 18-22).

In addition, Lowell teaches that polymeric adjuvant including those of polyacrylic acid and/or polymethacrylic acid (e.g., CARBOPOL, CARBOMER) poly(methylvinyl ether/maleic anhydride) copolymer, and their mixtures and copolymers in a final concentration of 0.01-0.5% (w/v) are effective for use conferring bioadhesive properties, e.g., enhances the delivery and attachment of antigens on or through the target mucous surface conferring mucosal immunity (page 15).

Likewise and even in the art of DNA vaccine, the concept of utilizing such adjuvants are well known in the prior art, e.g., see Wasmoen, column 4, Chavez, column 4, Gicquel, page 5.

One of ordinary skill in the art would have been motivated to employ any commercially available polymer-based adjuvant such as EMA in DNA vaccine composition taught by the combined cited references. One of ordinary skill in the art of polymer based adjuvant would have been motivated to employ EMA rather than just making one on the basis of the teaching of the combined cited references because of the ease and convenience of obtaining the adjuvants from the prior art and because of the well-known fact obtained from the totality of the prior art that EMA and CARBOPOL are effective adjuvants for use in any vaccination method including DNA vaccination methods.

Thus, the claimed invention as a whole was *prima facie* obvious.

Applicant's response (pages 8 and 9) has been considered by the examiner but is not found persuasive in view of the reasons set forth above. Applicant mainly argues that the concept of employing the claimed EMA and CARBOPOL as adjuvants in DNA vaccine composition is now taught therefore the use of teaching from protein vaccine wherein EMA or CARBOPOL is employed cannot be the basis for the rejection. The argument is not found persuasive in view of the reasons set forth in the above stated rejection.

Issue of the requested interview with Deborah Reynods and the examiner

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Given that the above are directed to the new grounds of rejection, and given that this office action must be prepared in time due to the already submitted response, the examiner respectfully submit that should applicant request an interview with the two above, applicant should call Deborah Reynolds for possible times that would be good to everyone. Insofar as the examiner's availability, the examiner will be on the vacation from 7/16/03-7/29/03, but will be available any time afterward. The good times that the examiner can be present in an interview are 11Am-12pm, or 3pm-4pm Monday-Wed, and Friday.

No claim is allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051**.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
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DAVE T. NGUYEN
PRIMARY EXAMINER